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Controlled Documents

Quality Implementing Procedure ID: OSTI-LLNL-QIP-6.0, Rev.0, Mod.0

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CONTROLLED DOCUMENTS

Quality Implementing Procedure ID: OSTI-LLNL-QIP-6.0, Rev. 0, Mod. 0 *Effective:* 2/25/05

1. PURPOSE

This Quality Implementing Procedure (QIP) establishes the administrative controls and process requirements for the identification, release, receipt, distribution, disposition, and file maintenance of Office of Science & Technology and International (OSTI)-Lawrence Livermore National Laboratory (LLNL) controlled documents and changes thereto. These controls ensure that documents are approved for release and are available at the location of use.

2. SCOPE

This QIP implements the requirements of the OSTI-LLNL Quality Assurance Plan, which has been developed to implement the U.S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM) *Quality Assurance Requirements and Description* (QARD), DOE/RW-0333P. The controls implemented herein are applicable to both quality-related (Q) and non-quality related (non-Q) documents. This QIP was prepared in accordance with OSTI-LLNL-QIP-5.0, *Preparing the Quality Assurance Plan and Quality/Technical Implementing Procedures.*

This procedure applies to the activities of the document Originator, the Records Coordinator, Controlled Copy Holders, and the Users of Controlled Documents during the document control process.

3. PROCEDURE

3.1 Control of Documents

The **Records Coordinator** shall:

A. Establish and maintain a Document Control Database, which shall be used to track the status and distribution of OSTI-LLNL controlled documents.

B. Establish a secure electronic folder, in which to store native files (the Master Copy) of controlled documents. The QA Manager shall determine access privileges for the folder. Access and security information shall be documented per OSTI-LLNL-QIP-SV.0, *Management of OSTI-LLNL Electronic Data.*

C. Establish electronic access to OSTI-LLNL procedures on the LLNL-EED web site. Documents available on the web page are not controlled and shall be labeled as "Information Only."

D. Maintain a paper copy of each document as the controlled document.

3.2 Document Type Identification

Controlled documents (e.g., QIPs, Technical Implementing Procedures (TIPs), Technical Work Plans (TWPs), Technical/Model Reports) that implement requirements, or specify technical or quality requirements, shall be created, revised, changed, reviewed for adequacy, and approved in accordance with a governing procedure for that type of document.

3.2.1 The **Originator** shall ensure the type of controlled document created is included as a document type in Attachment 1, Document Classifications and Types. If the document type is not identified in Attachment 1, coordinate the new document type with the Records Coordinator prior to approval and release of the document.

3.2.2 The **Records Coordinator** shall assign document types for categories of controlled documents that are controlled by an approved procedure.

3.3 Document Numbering/Identifiers

Controlled documents within a document type are required to have a unique identifier that is traceable through changes and revisions.

3.3.1 The **Records Coordinator** shall:

A. Assign a Document Identifier (DI) or sequence number in accordance with the specific document type.

B. Notify the Originator of the DI.

C. Enter controlled document information into the Document Control database.

D. Ensure that when a controlled document has been cancelled, its DI is not used for future controlled documents.

3.3.2 The **Originator** shall:

A. Obtain a unique document number for the initial issue of a controlled document from the Records Coordinator.

B. Ensure controlled documents are not renumbered without providing clear traceability from the old number to the new number (e.g., a reference to the old/new number in the revision history).

3.4 Submittal of Documents for Distribution

3.4.1 Prior to submittal to the Records Coordinator, the **Originator** shall ensure that:

- All documents and non-paper attachments meet the requirements of OSTI-LLNL-QIP-17.0, *Records Management.*

- The document has been appropriately reviewed and is administratively complete, technically accurate, and approved for use.

- If the native file is submitted, the native file has not been altered after approval.

- The document is legible. If any page of a document is deemed illegible and a better copy is not available, stamp the page as "Best Available Copy" and provide the Records Coordinator with a signed and dated statement explaining what the impact is of the illegible information.

- The document number and revision/modification is identified on every page of the document.

- Page accountability within the document, including attachments, has been established to ensure completeness. One of the following methods is preferred:

  - The total number of pages in the document is identified on the first page of the document as "Page 1 of N," where N is the total number of pages in the document (e.g., 1 of 10) and subsequent pages are sequentially numbered (e.g., 2 of 10, 3 of 10, etc). Attachments may be numbered separately from the main body of the document.

  - A Table of Contents, List of Effective Pages, or Index that establishes page accountability for documents, including the attachments.

- Traceability for changes in the document number is clearly maintained in the document, as well as on the Document Submittal form (Attachment 2).

- The governing document that controls the creation and change, including cancellation, for a type of document has been followed.

- If this is the initial issue of the document, a distribution list has been submitted to the Records Coordinator.

- If required, an effective date has been established by the Originator in coordination with the staff member identified in the governing procedure (e.g., QA Manager/Principal Investigator (PI) for QIPs and TIPs, respectively, per OSTI-LLNL-QIP-5.0).

- Submit approved document, revisions, cancellations, and changes to the Records Coordinator using Attachment 3, Document Submittal (this should be done no later than the next working day after the date of approval). This form is required for all controlled documents.

- To change a status of a document, follow the document's governing procedure and complete and submit Attachment 3.

3.4.2 The **Records Coordinator** shall accept the controlled document for distribution after the following has been completed:

A. Verify that the document agrees with the Document Submittal form and the form is administratively complete.

B. Review the document for correct document number, revision, modification or change, approval, inclusion of all pages, and appropriate page numbering.

C. If the document is provided in paper only, scan the document into pdf image format.

D. Update the document status in the Document Control database.

3.5 Distribution Control

The controlled copy shall be a paper copy maintained by the Records Coordinator. Unless a paper copy is required by the holder, distribution will be made through link to the electronic "Information Only" copy.

3.5.1 The **Originator** shall:

A. In collaboration with Records Coordinator, determine the distribution of the controlled document upon initial issue. Controlled documents used to perform work shall be distributed to, or made available to and used at, the work location.

B. Provide the Records Coordinator with a distribution list for initial issuance of a controlled document, indicating those copies to be distributed in paper form.

3.5.2 The **Records Coordinator** shall:

- Ensure that a distribution list is established for the initial issue of a controlled document.
- Submit the record copy of the controlled document to the Records Center (RC) in accordance with Section 4.0.
- If distributed electronically as "Information Only," make an electronic copy available within one working day of acceptance. If the controlled document has a later effective date, make the electronic copy available prior to or on the effective date.
- Ensure the approved controlled document is secured as the master copy in a manner that precludes revision to that copy.
- Distribute electronic notification to OSTI-LLNL Project Staff on or prior to the effective date, or within one working day of acceptance if no effective date is needed. The electronic notification will contain a link to

the "Information Only" copy for that controlled document, where applicable.

- Distribute paper copies with the appropriate Document Transmittal (Attachment 4) within three working days of acceptance. If the controlled document requires an effective date, distribute the document prior to or on the effective date.

- Maintain a distribution list as a controlled mechanism.

3.6 Maintenance of Controlled Copies

3.6.1 The **Records Coordinator** shall:

A. Store the Master Copy (electronic) of the controlled document in a secure electronic folder. This folder is the only source for an electronically controlled copy.

B. If the controlled document is not in electronic format, store a secured paper copy with access restricted to Quality Assurance Staff.

C. If a response to the Document Transmittal is not received within the requested timeframe, (usually two weeks) initiate a second notice. Remove the Document Holder from the controlled distribution list if the second notice is ignored.

3.6.2 For paper copies only, the **Controlled Copy Holders** shall:

A. Comply with the directions on the Document Transmittal form.

B. Destroy obsolete or superseded documents to prevent inadvertent use, or conspicuously mark them so they can be identified as "superseded" and separate them from the controlled copy.

C. Notify the Records Coordinator of address changes and when a paper copy is no longer needed.

3.6.3 For electronic notification, **Copy Holders** shall:

Notify the Records Coordinator of address changes and when the electronic notification is no longer needed.

3.7 Controlled and Working Copies

3.7.1 Controlled copies maintained in paper format shall contain a red stamp on the first page of the controlled document that provides confirmation that the document is a controlled copy and provides traceability to the individual responsible for ensuring the controlled document is current. Paper copies without this red stamp are not controlled and are used for reference or information only.

3.7.2 The **Records Coordinator** shall distribute controlled copies in paper form with (1) a red stamp on the first page of the document that indicates it is a controlled copy and (2) copy holder identification that provides traceability to the individual responsible for ensuring the copy is current.

3.7.3 When using a copy of a controlled document, **Users** shall ensure the current revision of the controlled document is used in performance of work by one of the following methods:

A. Comparing the revision level against the current Table of Contents maintained by the Records Coordinator

B. Comparing the revision level against a controlled copy, preferably a copy that is maintained by Records Coordinator

C. Communicating with the Records Coordinator to verify the latest revision.

3.8 Assessments

3.8.1 Every two years, as a minimum, the **Records Coordinator** shall assess distribution of controlled copies and provide controlled Copy Holders with an index of their holdings for verification.

3.8.2 Controlled **Copy Holders** shall verify the accuracy of the controlled documents assignment and assess the need to continue receiving the assigned documents in paper.

3.8.3 The **Records Coordinator** shall monitor controlled Copy Holder assessments to ensure their completion.

4. RECORDS

The records listed in Sections 4.1 and 4.2 shall be collected and submitted to the RC by in accordance with OSTI-LLNL-QIP-17.0 as individual records or included in a records package, as specified. The records listed in Subsection 4.3 shall be maintained and dispositioned by the Records Coordinator in accordance with OSTI-LLNL-QIP-17.0.

4.1 QA Records

Individual Records:

Controlled Document

4.2 Non-QA Long-Term Records

Individual Records:

Controlled Document

4.3 Non-QA Short-Term Records (three years or less retention)

- DI Request
- DI notification/verification
- Distribution list
- Document Submittal
- Document Transmittal
- Copy Holder's Reports and Feedback

5. RESPONSIBILITIES

5.1 The **Originator** is responsible to prepare the document in accordance with the appropriate governing procedure and submit the approved document to the Records Coordinator for control and distribution in accordance with this procedure.

5.2 The **Records Coordinator** is responsible for the Document Control functions as described in this procedure.

5.3 **Controlled Copy Holders** are responsible for paper controlled documents in their possession and for making controlled documents available at the workplace. They shall respond to the Document Transmittal in accordance with the instructions received and keep the Records Coordinator apprised of address changes.

5.4 **Users of Controlled Documents** are responsible to use the current version of any controlled document and to verify the current version with the Records Coordinator, if needed.

6. ACRONYMS AND DEFINITIONS

6.1 Acronyms

DI	Document Identifier
DOE	U.S. Department of Energy
ICN	Interim Change Notice
LLNL	Lawrence Livermore National Laboratory
OCRWM	Office of Civilian Radioactive Waste Management
OSTI	Office of Science & Technology and International
PI	Principal Investigator
PDF	Portable Document Format
Q	Quality Related
QA	Quality Assurance
QARD	Quality Assurance Requirements and Description
RC	Records Center

6.2 Definitions

Approval Date: The date the final signature is placed on a document by the authorized approval authority.

Cancellation: The act of removing a document from an active, controlled status.

Modification: A part of a controlled document that is modified and incorporated into the controlled document when revised. Modifications do not affect the revision level of a controlled document.

Controlled Copy: A copy that is updated through the distribution list maintained by Document Control or the electronic copy in the secure folder.

Controlled Copy Holder: An individual or organization that receives and maintains controlled documents and makes them available at the workplace.

Controlled Distribution: Distribution of controlled copies by the Records Coordinator to a controlled list of recipients. Distribution may be in paper copy or other media.

Controlled Document: A document that is prepared, reviewed, changed, and approved in accordance with established implementing documents; subject to controlled distribution; and subject to a defined change process.

Distribution List: A list that specifies the Document Holders to whom the Records Coordinator distributes controlled documents. This provides traceability to the individual responsible for maintaining the document in a current state and ensures users have the current revision available in the workplace.

Document Identifier (DI): A unique number assigned to a controlled document.

Document Transmittal: An information sheet containing the DI of the document, revision level, and title that, when signed by the holder, confirms receipt of the controlled document.

Document Type: A categorization of controlled documents released by the Records Coordinator. See Attachment 1, Document Types.

Effective Date: The date upon which implementation of an implementing document becomes mandatory.

Master Copy: A copy of a controlled document maintained by the Records Coordinator from which controlled copies can be reproduced. This copy may be in electronic form and maintained on-line in a secure folder or on paper.

Status: A code designator that indicates the status of a controlled document or limits the use of a controlled document. See Attachment 2, Status Codes, for a sample listing of status codes.

7. REFERENCES

DOE/RW-0333P, *Quality Assurance Requirements and Description*

OSTI-LLNL-QIP-5.0, *Preparing the Quality Assurance Plan and Quality/Technical Implementing Procedures*

OSTI-LLNL-QIP-6.1, *Document Review*

OSTI-LLNL-QIP-17.0, *Records Management*

OSTI-LLNL-QIP-SV.0, *Management of OSTI-LLNL Electronic Data*

8. ATTACHMENTS

Attachment 1 Document Classification and Types
Attachment 2 Status Codes
Attachment 3 Document Submittal
Attachment 4 Document Transmittal

9. REVISION HISTORY

2/25/05 Revision 0, Modification 0
Initial issue.

10. APPROVALS

Preparer: Lijl Gouveia — Date: 2/25/05

Technical Reviewer: QINHONG HU — Date: 2/25/05

QA Reviewer: VICTOR J. BARISH SR — Date: 2/25/05

Project Manager: DAVID B. McCALLEN — Date: 2/25/05

DOCUMENT CLASSIFICATIONS AND TYPES

Administrative Documents

Directive

Policy

Guideline

Standard

Change Documents

Modification

Expedited Modification

Interim Change Notice

Errata

Plans/Program Descriptions Documents

Data Qualification Plan

Technical Work Plan

QA Plan

Procedures/Instructions

Quality Implementing Procedure

Technical Implementing Procedure

Reports

Technical Report

Model Report

STATUS CODES

Code	Definition
Approved/Issued for use	Used to indicate a controlled document, including a revision or modification, which has been approved for use and is active.
Cancelled/Void	Used to indicate a controlled document that no longer requires controlled distribution.
Superseded	Used to indicate a document that has been replaced by another document or new revision.
Reactivate	Used to indicate documents taken from a cancelled/voided status back to an approved/issued for use status.

OSTI-LLNL
DOCUMENT SUBMITTAL

Complete only applicable items

1. QA: NA
2. Page 1 of 1

TO BE COMPLETED BY ORIGINATOR/RECORDS COORDINATOR (OR DESIGNEE)

3. Document ID	4. Revision/Mod or ICN	5. Document QA Designation ☐ QA: QA ☐ QA: NA

6. Document Title

7. Document Submittal Date	8. Document Approval Date	9. Document Effective Date

10. Does this document supersede any documents?
☐ Yes ☐ No

If yes, list any affected document number(s):

11. Document Status
- ☐ Approved/Issue for Use
- ☐ Canceled/Void
- ☐ Superseded
- ☐ Reactivate

12. Access Restrictions for Document (applicable forms attached. Check all that apply)
- ☐ Yes ☐ No Unclassified Nuclear Information
- ☐ Yes ☐ No Sensitive Unclassified
- ☐ Yes ☐ No Safeguards
- ☐ Yes ☐ No Copyright Protected Material
- ☐ Yes ☐ No Proprietary

13. Media of Submittal (check all that apply)
- ☐ Yes ☐ No Paper Copy
- ☐ Yes ☐ No Native File
- ☐ Yes ☐ No PDF File
- ☐ Yes ☐ No Media attachments

14. This document was created, modified, or changed in accordance with governing procedure #:

15. Distribution Information (Note: All distribution will be electronic and Information Only, unless otherwise indicated).

If Initial issue
- ☐ Use names below
- ☐ Use attached list (attach separately)
- ☐ No distribution to individuals

Or, if Revision/Change to Existing Document:
- ☐ Add names below
- ☐ Add names on attached list (provide separately)
- ☐ Maintain distribution (no additions)

This signature confirms that this document has been appropriately reviewed for any access restrictions and has been approved for release within those restrictions. Appropriate documentation is attached that supports the reviews, if applicable.

16. Submitted By (Print Name/Sign/Date)

TO BE COMPLETED BY OSTI – LLNL RECORDS COORDINATOR (OR DESIGNEE)

17. Received by (Print Name/Sign/Date)

18. Accepted by (Print Name/Sign/Date)

19. Electronically posted by (Print Name/Sign/Date)

DOCUMENT SUBMITTAL INSTRUCTIONS

Originator or Records Coordinator:

1. Defaults to N/A.
2. Enter the page number.
3. Enter the document number.
4. Enter the revision/modification number of the document.
5. Select the QA designator of the document and check applicable box.
6. Enter the document title.
7. Enter the date the document was submitted.
8. Enter the date the document was approved (last approval signature).
9. Enter the effective date of the document, taken from the document (or mark N/A if there is not an effective date).
10. Identify if the document supersedes any other documents. If yes, list the affected document numbers, revision, and modification/Interim Change Notice.
11. Select the status of the document and check the applicable box.
12. Identify access restrictions, if any, and check all applicable boxes.
13. Indicate the type of media submittal.
14. Enter the DI, revision, and modification of any controlling procedures, if applicable.
15. Indicate distribution information.
16. Print name, sign, and date.

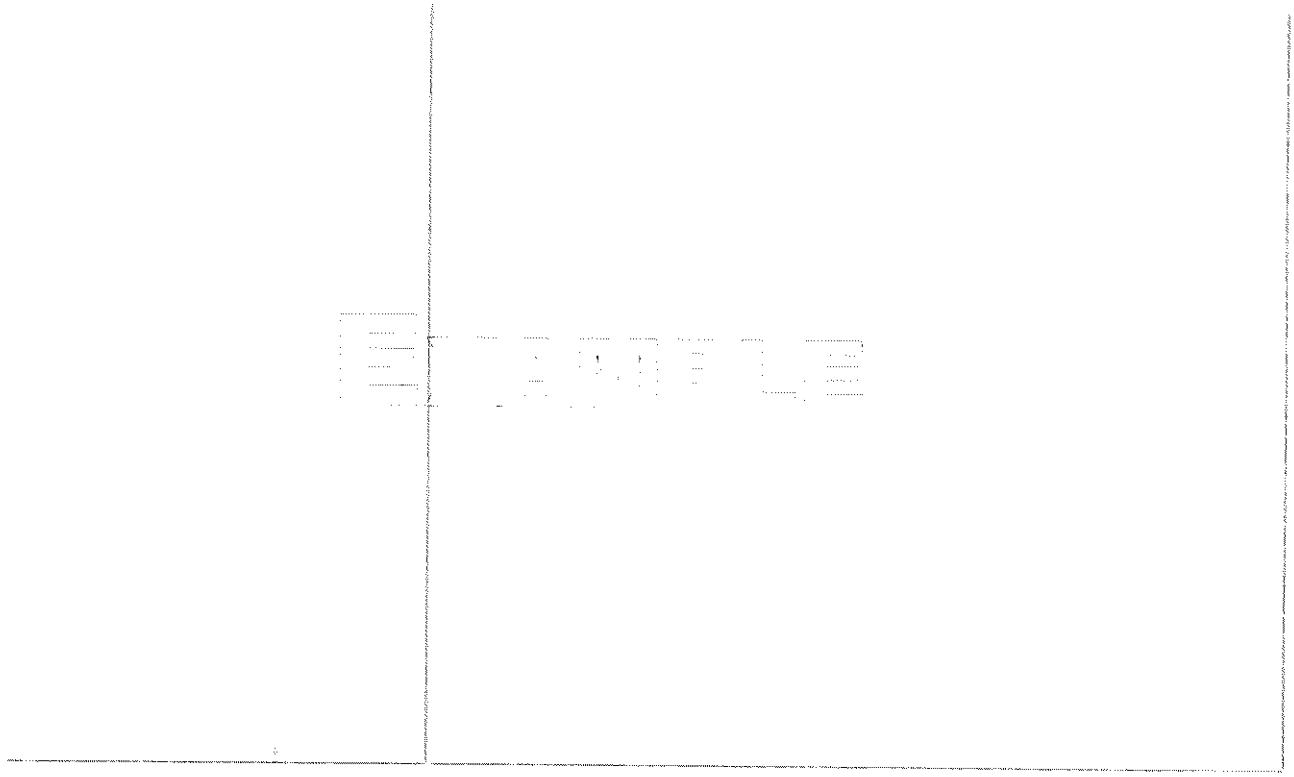
Records Coordinator (or Designee):

17. Print name, sign, and date upon receipt.
18. Print name, sign, and date upon acceptance.
19. Print name, sign, and date upon electronic posting, or mark N/A if not applicable.

OSTI-LLNL Document Transmittal

Name: **Holder Number**

Assigned Controlled Documents



Return the signed Transmittal, and direct any questions regarding these instructions, to the Records Coordinator

Due Date for Return of this Transmittal

Records Coordinator (Print)

Phone and FAX
(925) 424-4640 Document Control Questions
(925) 422-0540 FAX

Certification: By signing this Document Transmittal you are attesting that 1) if a document has been canceled, superseded, or is no longer needed, the document has been marked obsolete, canceled, or superseded, or destroyed, so it is not used to perform work (if the document contains sensitive unclassified information, or incorporates copyright material, return the document to Document Control with the Document Transmittal); 2) any changes received on this distribution have been posted to the applicable documents.

Receipt Acknowledgement and Certification

Copy Holder Name (Print and Sign) Date